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I, JONNE YABSLEY, TEAM LEADER EXAMINATION SUPPORT AND SALES hereby certify that annexed is a true copy of the Provisional specification in connection with Application No. 2002951738 for a patent by COCHLEAR LIMITED as filed on 30 September 2002.

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AUSTRALIA

Patents Act 1990

Cochlear Limited

PROVISIONAL SPECIFICATION

Invention Title:

Feedthrough with extended conductive pathways

The invention is described in the following statement:

Field of the Invention

The present invention relates to an electrical connector system for electrical products. More specifically, the present invention relates to an electrical connector having one or more hermetically sealed but electrically conducting feedthroughs extending therethrough. The connector can be used in devices such as biosensors and implantable devices. Examples of implantable devices include the implantable component of a cochlear implant hearing prosthesis.

Background of the Invention

The term 'feedthrough' as used herein refers to the provision of an electrically conducting path extending from the interior of a hermetically sealed container or housing to an external location outside the container or housing. Typically, a conductive path is provided through the feedthrough by an electrically conductive pin, which is electrically insulated from the container or housing by an electrically insulating body surrounding the pin.

A feedthrough device therefore allows one or more electrical connections to be made with electronic circuitry or components within the hermetically sealed container or housing, whilst protecting the circuitry or components from any damage or malfunction that may result from exposure to the surrounding environment.

There are many applications that require feedthrough devices to provide an electrically conducting path whilst also sealing the electrical container or housing from its ambient environment. Historically, the first such devices were widely used in vacuum technology allowing for the transfer of signals between chambers of differing pressures. In such applications, the vacuum tubes had to be sealed because they could only operate under low-pressure conditions.

Over time, and with the advent of electrical devices capable of being implanted in body tissue to provide therapy to a patient, such as cardiac pacemakers, defibrillators and cochlear implants, the need to provide feedthrough devices with improved hermeticity has become increasingly

important. As the environment of living tissue and body fluids is quite corrosive and the implants may contain materials which may be detrimental to the patient, a hermetic feedthrough device is used to provide a barrier between the electronic components of the device and the external corrosive environment of the human body. With implantable medical devices in particular, it is critically important that the hermetic seal of the device be physically rugged and long lasting. For this reason, stringent requirements are imposed on the hermeticity of an implanted device, typically requiring a seal that provides a leakage rate of less than 10^{-8} cc/sec.

In this regard, in medical implant applications such as those used in pacemaker devices and cochlear implants, the feedthroughs typically consist of a ceramic or glass bead that is bonded chemically at its perimeter through brazing or the use of oxides, and/or mechanically bonded through compression, to the walls of the sealed package. A suitable wire or other conductor passes through the centre of the bead, and this wire or conductor must also be sealed to the bead through chemical bonds and or mechanical compression. In this regard, the feedthrough is typically cylindrical and the wire(s) or conductor(s) mounted within the bead are centred or mounted in a uniform pattern, centrally within the bead.

Other materials and processes are known for making feedthroughs, for example, from aluminium oxide ceramic and binders. These types of feedthroughs are widely used for cardiac and cochlear implants. One of the processes for making such a feedthrough consists of pre-drilling holes in a sintered ceramic plate and then forcing electrical conductive pins through the holes. However, this method does not necessarily guarantee a hermetic seal, resulting in unsatisfactory leakage rates. A second method involves inserting the conductive pins into an unsintered (or 'green') ceramic plate and then curing the assembly by firing to achieve a hermetic seal. A major disadvantage of this last method is that, historically the manufacturing process has been performed by hand. Such a method of manufacture can lead to inaccuracies and be time consuming, expensive and labour intensive. Moreover, the feedthrough devices resulting from such a process do not necessarily have precisely positioned electrical conductors, with the position of the conductors being greatly dependent upon the process itself. Further, as the conductors

are typically wires being of a general cylindrical shape and configuration, the size and shape of the conductor extending from the insulative material of the feedthrough is generally the same as the conductor embedded in the insulative material of the feedthrough. This aspect has made it difficult to design feedthrough devices wherein the shape of the conductor element differs over the length of the conductor such that the external ends of the conductors are maximised to suit the specific purpose of the feedthrough device.

As implantable devices continue to develop and become thinner and smaller and more electronically sophisticated, the requirements of the feedthrough have also increased. In cochlear implants in particular, where there are now typically 22-24 electrode leads, there is a need for 22-24 conductive pins passing through the feedthrough device. As the desire for more electrodes and smaller feedthroughs increases, the demands placed upon the design of the traditional feedthrough also increases. The problems in fabricating such a feedthrough device on such a large scale are therefore quite significant, especially when one considers the relatively high degree of labour intensity and specialisation of the current fabricating methods.

While the above described prior art feedthrough devices and fabrication methods have proven successful, it is a relatively slow and labour intensive process to manufacture such devices. The method of manufacture of the feedthrough also presents limitations in the number of conductors that can pass through the feedthrough and the position and configuration of such conductors within the feedthrough device, particularly in applications where this number needs to be maximised.

The present invention is directed to a connector and electrically conducting feedthrough arrangement that addresses at least some of the problems with prior art systems.

Any discussion of documents, acts, materials, devices, articles or the like which has been included in the present specification is solely for the purpose of providing a context for the present invention. It is not to be taken as an admission that any or all of these matters form part of the prior art base or were

common general knowledge in the field relevant to the present invention as it existed before the priority date of each claim of this application.

Summary of the Invention

Throughout this specification the word "comprise", or variations such as "comprises" or "comprising", will be understood to imply the inclusion of a stated element, integer or step, or group of elements, integers or steps, but not the exclusion of any other element, integer or step, or group of elements, integers or steps.

According to a first aspect, the present invention is an electrically conducting feedthrough comprising:

a relatively electrically insulative member having a first face and at least a second face; and

at least one electrically conductive member extending through at least a portion of the electrically insulative member from the first face to the second face;

wherein said at least one conductive member is non-linear between said first face and said second face.

According to a second aspect, the present invention is an electrically conducting feedthrough comprising:

a relatively electrically insulative member having a first face and at least a second face; and

at least one relatively electrically conductive member extending through at least a portion of the electrically insulative member from the first face to the second face;

wherein said at least one conductive member has a length between said first face and second face that is greater than the shortest distance between said first face and said second face.

According to a third aspect, the present invention is an electrically conducting feedthrough comprising:

a relatively electrically insulative member having a first face and at least a second face; and

at least one relatively electrically conductive member extending through at least a portion of the electrically insulative member from the first face to the second face;

wherein said at least one conductive member has a shape having varying cross-sectional area along the length thereof such that an interface path between said member and said electrically insulative member is greater than the shortest distance between said first face and said second face.

In these aspects, the relatively electrically insulative material is preferably a ceramic material or hermetic glass material, suitable for use in a feedthrough application.

The feedthrough of the present invention has the capability of being made sufficiently small to meet the size requirements for implantable devices, such as cochlear implant systems, whilst also ensuring that the degree of hermeticity of the feedthrough is such to ensure that the feedthrough will not be a source of leakage in either direction through the casing or housing of such a device during the expected lifetime of that implant.

In one embodiment, the first face and second face of the insulative member can face outwardly in opposite directions. In one embodiment, the first and second faces can be substantially parallel or parallel. The first face is preferably the outer face of the feedthrough and the second face is preferably the inner face of the feedthrough.

In one embodiment, the feedthrough preferably has a plurality of electrically conductive members extending through the insulative member from said first face to said second face. In one embodiment, each of the conductive members have the same configuration. In another embodiment, only some of the conductive members may have the same configuration while one or others have a different configuration.

In a further embodiment, said one or more conductive members can undergo a first change of direction between the first face and the second face of the insulative member. In another embodiment, said one or more conductive

members can undergo two or more changes of direction between the first face and the second face of the insulative member.

In yet another embodiment, said one or more conductive members undergo a change of direction in a nominal plane extending at an angle, such as a right angle, to one or both faces of the insulative member. In another embodiment, said one or more conductive members can undergo a change of direction into a direction out of a nominal plane extending at an angle, such as a right angle, to one or both faces of the insulative member. The conductive member can undergo more than one change of direction out of said nominal plane.

Each change of direction can be at a right angle to the preceding direction of the conductive member. In another embodiment, the change of direction can be at a different angle than a right angle to that of the preceding direction.

In another embodiment, the change of direction can be abrupt. In another embodiment, the change of direction can be smoothly curved. In another embodiment, a particular conductive member can undergo a combination of abrupt and/or smoothly curved changes of direction.

In yet another embodiment, said one or more conductive members can have a shape of varying cross-section over the length thereof. In this regard, the conductive members may extend linearly or non-linearly through the insulative member, however, the interface path between the conductive members and the insulative member is maximised, thereby reducing the effective leakage pathway of the feedthrough device. The conductive members may have a stepped shape providing a zig-zag interface pathway or may have a screw-thread shape providing an equally extended interface pathway.

In one embodiment, the electrically conductive members can be formed from a film or shim of an electrically conductive metal or metal alloy. In a preferred embodiment, the film or shim is formed from a biocompatible metal or metal alloy. In one such embodiment, the electrically conductive structure can be formed from a film or shim of platinum.

In one embodiment, the electrically conductive members can be formed using a method comprising the steps of:

(i) forming an electrically conductive structure comprising a sacrificial component and non-sacrificial component;

(ii) coating a relatively electrically insulative ceramic member on to at least a portion of the non-sacrificial component; and

(iii) removing at least a portion of the sacrificial component.

In this embodiment, the film or shim of platinum can be formed into a shape comprising the sacrificial component and the non-sacrificial component of the electrically conductive structure. In this embodiment, it will be appreciated that that portion of the film or shim comprising the non-sacrificial component may comprise more than one portion of the film or shim. Similarly, that portion of the film or shim comprising the sacrificial component may comprise more than one portion of the film or shim.

In one embodiment, the electrically conductive component may comprise a film or shim having a shape comprising two or more separated members extending between respective transverse support members. In a further embodiment, the film or shim can have at least ten separated members extending between the respective support members. In a further embodiment, the support members can be in a side-by-side relationship with respect to each other.

The separation of the members is preferably such that the insulative member material can be coated between the members and so prevent electrical conduction between the respective members at completion of the method as defined herein.

In a preferred embodiment, the shape of the electrically conductive component comprising what will become the conductive members can be formed in step (i) by punching the shape, using a suitable shaped and dimensioned punching tool, from a film of platinum.

In another embodiment, the shape of the electrically conductive component can be formed in step (i) by using electrical discharge machining (EDM), which is also known as spark erosion, to remove unwanted portions of the sheet. In a preferred embodiment, the EDM equipment used in the process has a cutting tool comprising an electrode. The cutting tool does not physically cut the sheet but instead relies on the equipment generating a series of electrical discharges between the electrode and the sheet in a dielectric fluid. The electrical discharges serve to vaporise the sheet in the region adjacent the cutting tool.

In a preferred embodiment, the cutting tool has a size and shape that matches the size and shape of the portion of the sheet to be removed from the sheet during the machining steps. In this embodiment, it is preferred that the tool is brought adjacent the sheet at a number of different locations so as to remove differing portions of the sheet. This multiple use of the tool preferably serves to gradually build up the pattern of the electrically conductive component comprising the conductive members.

In a preferred embodiment, the cutting tool can be used to form a series of discrete conductive members from a sheet of platinum or other suitable metal. The conductive members are preferably disposed in a side-by-side arrangement.

In another embodiment, the cutting tool can be used to form a series of discrete conductive members from a plurality of sheets of platinum or other suitable material stacked one atop the other. In this manner, a large number of electrically conductive components can be prepared with a single cutting motion of the cutting tool. In such an embodiment, a method known as "wire cutting" can be employed. This method operates in a similar manner to EDM/spark erosion methods wherein a wire is passed through a stack of sheets or foils of conductive material with this wire becoming the electrode causing the erosion of material adjacent the electrode. By using this method a plurality of foils can be patterned simultaneously, resulting in a process that is capable of mass producing patterned conductive foils to be used to create the feedthrough device of the present invention.

In this embodiment, at least a portion of each of the members extending between the support members are coated with the insulative member. The insulative member can be alumina but other suitable ceramic types can be envisaged.

In one embodiment, the insulative member can be coated on the non-sacrificial component and not coated or moulded on to at least a portion of the sacrificial component of the conductive structure. Still further, step (iii) of the method can comprise removing at least that portion of the sacrificial component on to which the insulative member has not been coated.

The step of coating the electrically conductive structure preferably comprises a step of mounting or clamping the conductive structure in a mould and then moulding a coating of the insulative material, such as a ceramic, on and/or around the conductive structure.

Where the conductive structure comprises a plurality of conductive members formed from a film or shim of platinum, the insulative material is preferably coated or moulded around at least a portion of the members of the conductive structure. In this embodiment, said portion of the members comprises a portion of the non-sacrificial component of the electrically conductive structure. While this embodiment envisages the film or shim being shaped as desired prior to clamping or mounting in the mould, it will be appreciated that a film of platinum could be firstly mounted or clamped in the mould and then shaped or punched as required prior to the moulding or coating step.

In a preferred embodiment, the mould can comprise an injection mould. In one embodiment. step (ii) can comprise a step of using powder injection moulding (PIM) to mould the insulative material around the desired portion of the conductive structure.

In this moulding process, insulative material, such as relatively fine ceramic powder, is mixed with a carrier chemical, typically called binder, and homogenised to create a feedstock for the injection mould. The presence of the binder serves to make the feedstock sufficiently fluid to be used in an

injection moulding process. Once moulded, the insulative material can be allowed to at least partially set. The resulting moulded part is hereinafter called the green body.

Once the green body is formed, the sacrificial component of the electrically conductive structure can be removed. During this step, it is possible that a portion of the green body may also need to be removed. In one embodiment, the sacrificial component can be removed by being cut, abraded or ground away. In this regard, physical cutting with a knife, or laser cutting techniques, are envisaged.

Where the electrically conductive structure comprises the plurality of members extending between the transverse members, the sacrificial component preferably includes at least the transverse members so leaving a plurality of electrically insulated members extending through the green body.

In a still further embodiment, the method can comprise an additional step of debinding the green body. In this step, any binder in the green body is preferably extracted from the insulative material. In one embodiment, this step can comprise a chemical debinding in which the green body is soaked in a suitable solvent. In another embodiment, this step can comprise exposing the green body to a relatively elevated temperature. This temperature is preferably sufficient to boil off the binder from the green body while not causing the green body to undergo sintering. In one embodiment, the temperature is between about 150°C and 200°C.

During the debinding step, the insulative material preferably shrinks in dimension. This debinded insulative material member is hereinafter called a brown body.

When ready, the brown body can undergo a sintering step. The sintering step preferably comprises exposing the brown body to a suitable elevated temperature. In one embodiment, the sintering step can comprise exposing the brown body to a sintering temperature of about 1700°C. During the sintering step, the insulative member undergoes further shrinkage and becomes relatively more robust. The shrinkage of the insulative member also serves to

form an hermetic seal at the interface between the embedded platinum members and the surrounding sintered insulative member.

Once complete, the insulative member with the conductive members extending therethrough can be brazed into an orifice in the wall of a unit adapted to receive the feedthrough. Electrical connection can then be made to each end of the respective conductive members as required to form respective electrical conductive paths through the insulative body of the feedthrough.

In one embodiment, the feedthrough can be brazed into the wall of an electrical device, such as an implantable stimulator unit of a medical implant device. In a preferred embodiment, the feedthrough can be adapted to be used with a cochlear implant hearing prosthesis to provide electrical conduction between the circuitry within the implantable stimulator unit and the intracochlear or extracochlear electrodes and/or the implantable receiver coil.

Each feedthrough preferably has sufficient conductive members embedded therein to ensure there are sufficient connectors to suit the desired application. In a cochlear implant application, the feedthrough would have to have sufficient conductive members embedded therein to ensure that there are sufficient connectors for each of the electrode channels of the intracochlear electrode array, one or more extracochlear electrodes, and the inputs from the receiver coil.

In one embodiment, the present invention is a feedthrough for an implantable component comprising a ceramic member having a plurality of electrically conductive platinum members extending therethrough. The platinum members are hermetically encased within the ceramic in a way that allows electrical connection through the feedthrough while preventing transfer of bodily fluids from outside the component into the interior of the component.

Brief Description of the Drawings

By way of example only, preferred embodiments of the invention are now described with reference to the accompanying drawings, in which:

Fig. 1 is a plan view of one embodiment of a electrically conductive structure for use in the method according to the present invention;

Fig. 2 is an enlarged plan view of a single conductive member of another embodiment of a conductive structure according to the present invention;

Fig. 3 is an enlarged plan view of a single conductive member of another embodiment of a conductive structure according to the present invention;

Fig. 4 is an enlarged view of a single conductive member of another embodiment of a conductive structure according to the present invention;

Fig. 5 is a perspective view of the conductive structure of Fig. 1 overmoulded with a ceramic member;

Fig. 6 is a cross-sectional view of two different conductive structures of a feedthrough according to the present invention wherein the interface between the conductive structures and the insulative material is non-linear; and

Fig. 7 is an enlarged view of one of the interfaces of Fig. 6.

<u>Preferred Mode of Carrying out the Invention</u>

Fig. 1 depicts one type of electrically conductive structure that can be used in the manufacture of a feedthrough according to the present invention. The depicted electrically conductive structure is formed from a film or shim 21 of biocompatible platinum. Other suitable electrically conductive metals or metal alloys can be envisaged.

In Fig. 1, the film or shim 21 of platinum is formed into a shape comprising a sacrificial component and a non-sacrificial component. In this embodiment, the electrically conductive structure comprises a plurality of separated non-linear members 22 extending between respective parallel transverse support members 23,24.

The separation of the non-linear members 22 is such that the insulative member (such as a ceramic) when moulded around the members 22 can also move between the members 22 and so prevent electrical conduction between the respective non-linear members 22 at completion of the method 10.

In the depicted embodiment, the shape of the electrically conductive structure 21 is formed by punching the shape, using a suitable shaped and dimensioned punching tool, from a film of platinum. It is envisaged that this shape could also be formed by a variety of material removal methods, such as electrical discharge machining (EDM), micro-knifing and/or laser cutting.

Fig. 1 depicts the non-linear members 22 as having two relatively abrupt right angle changes of direction at corners 25 and 26. Alternative elongate but non-linear conductive members 22 are depicted in Figs. 2, 3, and 4.

In Fig. 2, the non-linear member 22 undergoes two changes in directions at corners 25a and 26a. In this embodiment, the changes in direction are relatively smoothly curved. As depicted in Fig. 3, the non-linear member can undergo more than two changes in direction. Other suitable configurations can be envisaged.

In Fig. 4, the conductive member is formed and then twisted into a third dimension before being clamped and then placed in a mould. The insulative member can then be moulded around the spiral conductive member 22. Again, other configurations of the conductive member extending through the insulative member in a third dimension can be envisaged.

Fig. 5 depicts the conductive structure of Fig. 1 where at least a portion of each of the non-linear members 22 extending between the support members 23,24 are coated or overmoulded with an insulative ceramic member 35 described in more detail below.

Fig. 6 depicts an alternative embodiment of the present invention. In this embodiment, conductive members 50 are shown extending from one face 51 of an insulative member 35 to another face 52. In this embodiment, the conductive members 50 are substantially linear however the surfaces of the

conductive members 50 are provided with extended material to produce a shape that lengthens the interface path between the conductive material and the insulative material 50. As shown, possible shapes of the conductive members according to this embodiment include having a stepped outer surface or a screw-thread shaped member. The purpose of providing such a shaped conductive member is to substantially increase the leakage pathways of the feedthrough device.

In the depicted embodiment, the step of moulding the ceramic 35 around the electrically conductive structure comprises a step of mounting or clamping the conductive structure in a mould and then moulding the ceramic on and/or around the conductive structure.

In a preferred embodiment, the mould can comprise an injection mould. In one embodiment, powder injection moulding (PIM) can be used to mould the ceramic around the desired portion of the conductive structure. In this moulding process, fine ceramic powder is mixed with a binder and homogenised to create a feedstock for the injection mould. The presence of the binder serves to make the feedstock sufficiently fluid to be used in an injection moulding process. Once moulded, the ceramic can be allowed to at least partially set and form a green body.

In the embodiment shown in Figure 7, the effect of such a design on the feedstock properties is shown. In this embodiment, which is an enlargement of the section shown in Fig. 6, the feedstock is designed to flow inside the stepped cavities of the conductive member to form a bond with the surface of the conductive member along the entire length of the conductive member. In this embodiment, the conductive member can have dimensions of x and y within the range of 10-50μm. In this range, the feedstock is capable of filling such cavities with standard powder injection moulding techniques to provide a well sealed interface. It is envisaged that with improvements in the capabilities of the feedstock and associated equipment, even smaller cavities will be able to be successfully employed.

Once the green body is formed, the sacrificial component of the electrically conductive structure can be removed. In the depicted embodiment,

the sacrificial component can be removed by laser cutting. Other suitable techniques, such as cutting or abrading techniques, are also envisaged.

In the embodiment depicted in Figs 1-4, the sacrificial component comprises the transverse members 23,24. Once these are removed, a plurality of respectively electrically insulated non-linear members 22 remain extending through the green body 35.

The method of forming the feedthrough further comprises a step of debinding the green body. In this step, the binder in the green body is extracted from the ceramic. In one embodiment, this step can comprise a chemical debinding in which the green body is soaked in a suitable solvent. In another embodiment, this step can comprise exposing to a relatively elevated temperature. This temperature is preferably sufficient to boil off the binder from the green body while not causing the green body to undergo sintering. In one embodiment, the temperature is between about 150°C and 200°C.

During the debinding step, the ceramic preferably shrinks in dimension to form a brown body.

When ready, the brown body can undergo a sintering step. The sintering step preferably comprises exposing the brown body to a suitable elevated temperature. In one embodiment, the sintering step can comprise exposing the brown body to a sintering temperature of about 1700°C. During the sintering step, the ceramic member undergoes further shrinkage and becomes relatively more robust. The shrinkage of the ceramic also serves to form an hermetic seal at the interface between the embedded platinum members and the surrounding sintered insulative member.

Once complete, the insulative member with the platinum members extending therethrough can be brazed into an orifice in the wall of a unit adapted to receive the feedthrough. Electrical connection can then be made to each end of the respective platinum members as required to form respective electrical conductive paths through the insulative body of the feedthrough.

Such a feedthrough can be adapted to be brazed into the wall of an implantable stimulator unit of a cochlear implant hearing prosthesis. In this embodiment, the feedthrough can be adapted to provide electrical conduction between the circuitry within the implantable stimulator unit and the intracochlear or extracochlear electrodes, and/or the implantable receiver coil.

Each feedthrough preferably has sufficient platinum members embedded therein to ensure there are sufficient connectors for each of the electrode channels of the intracochlear electrode array, one or more extracochlear electrodes, and the inputs from the receiver coil.

In one embodiment, the present invention is a feedthrough for an implantable component comprising a ceramic member having a plurality of electrically conductive platinum members extending therethrough. The method of forming this feedthrough ensures the platinum members have a sufficient length and are encased within the ceramic in away that allows electrical connection through the feedthrough while preventing transfer of bodily fluids from outside the component into the interior of the component.

It will be appreciated by persons skilled in the art that numerous variations and/or modifications may be made to the invention as shown in the specific embodiments without departing from the spirit or scope of the invention as broadly described. The present embodiments are, therefore, to be considered in all respects as illustrative and not restrictive.

Dated this thirtieth day of September 2002

Cochlear Limited
Patent Attorneys for the Applicant:

F B RICE & CO

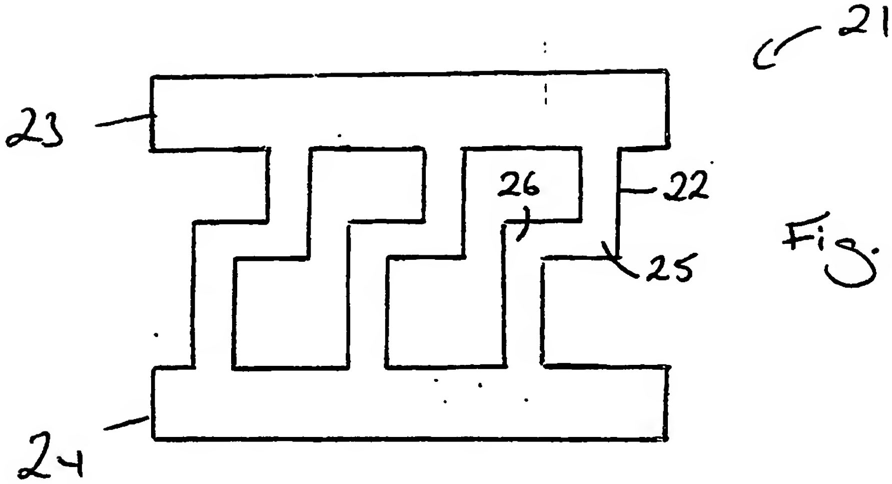

Fig. 1

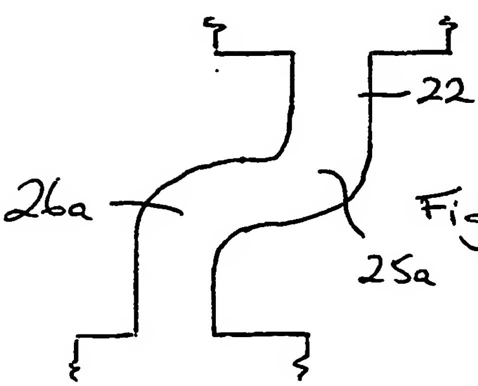

Fig. 2

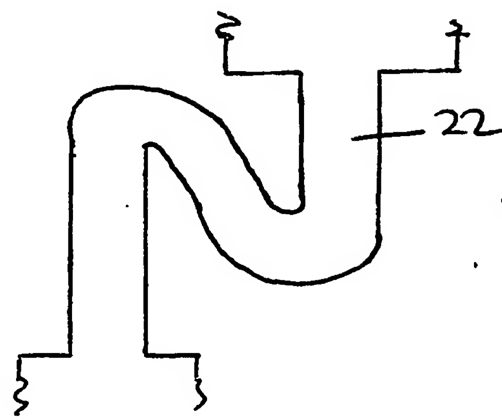

Fig. 3

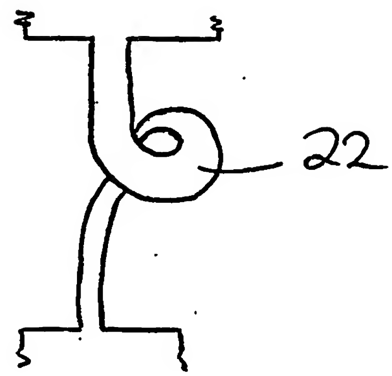

Fig. 4

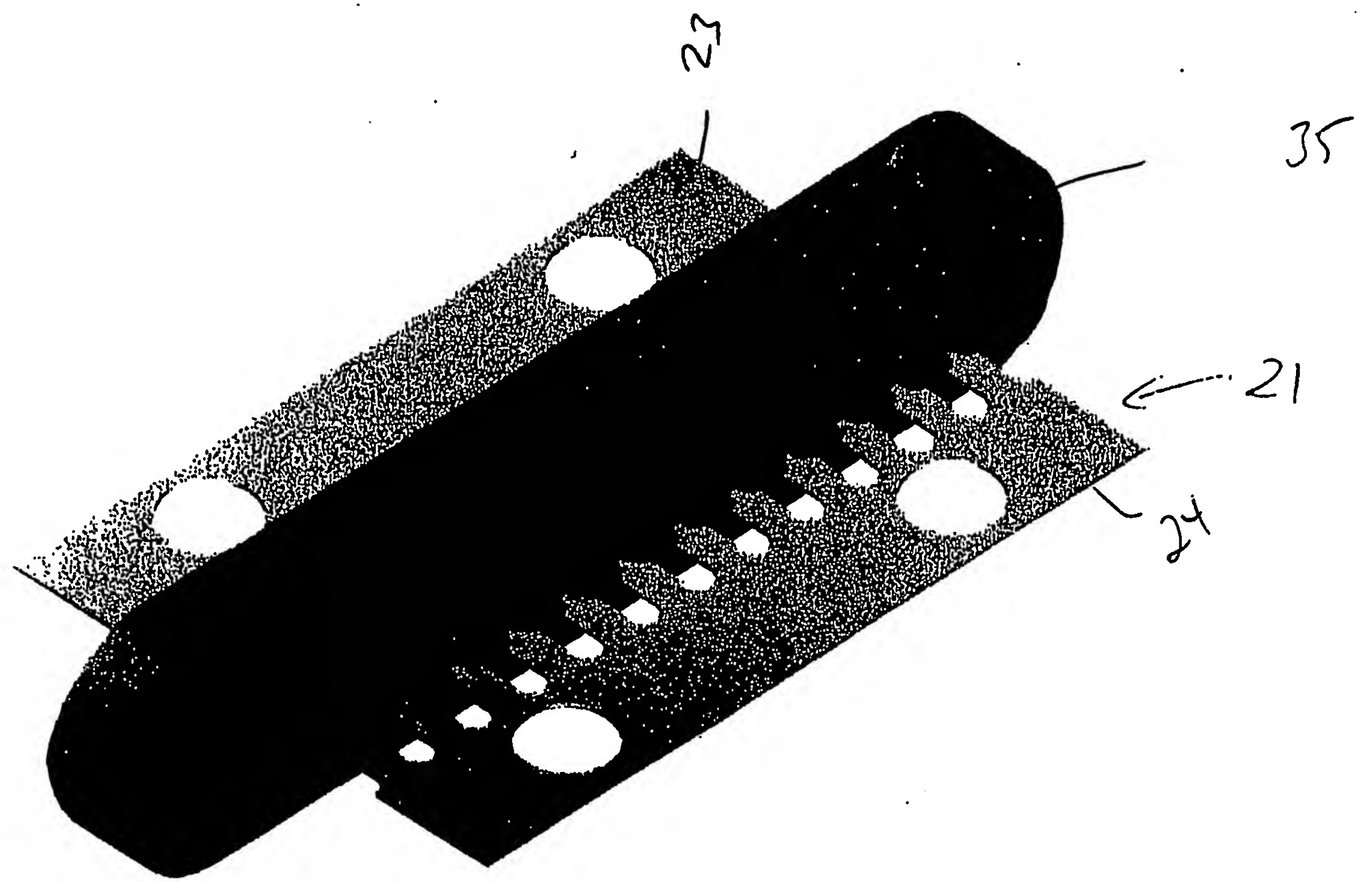

Fig. 5

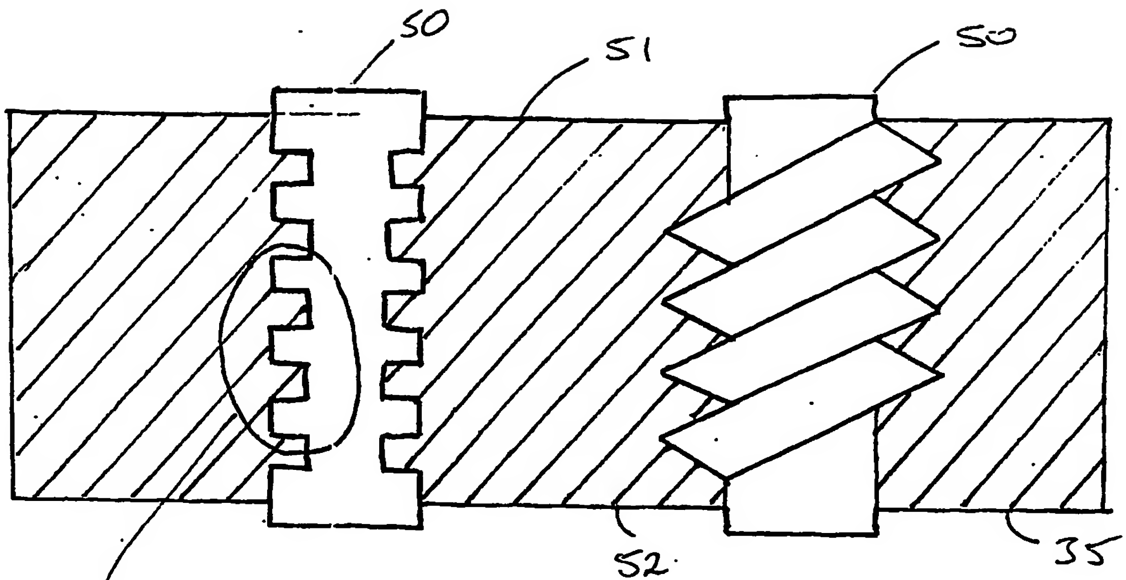

Figure 6

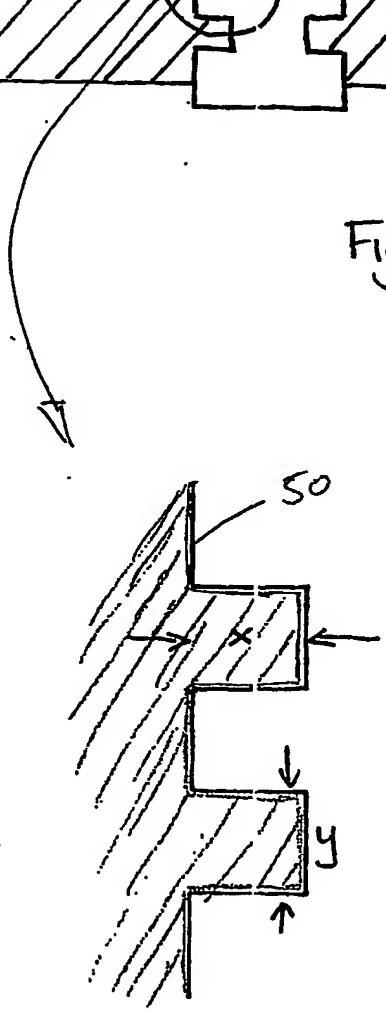

Figure 7.